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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/808,004	03/24/2004	Mary L. Owens	58516US003	4652

32692 7590 04/06/2006

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EXAMINER	
FETTEROLF, BRANDON J	
ART UNIT	**PAPER NUMBER**
1642	

DATE MAILED: 04/06/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/808,004	OWENS ET AL.	
	Examiner	Art Unit	
	Brandon J. Fetterolf, PhD	1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-16* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-16* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *24 March 2004* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *8/20/2004*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Owens et al.

DETAILED ACTION

Application Status

Claims 1-16 are currently pending and under consideration.

Information Disclosure Statement

The information disclosure statement filed 8/20/2004 fails to comply with 37 CFR 1.98(a)(2), which requires a legible copy of each cited foreign patent document; each non-patent literature publication or that portion which caused it to be listed; and all other information or that portion which caused it to be listed, i.e., JP 11-80156 and JP 11-222432. Moreover, the information disclosure statement fails to comply with 37 CFR 1.98(a)(3) because it does not include a concise explanation of the relevance, as it is presently understood by the individual designated in 37 CFR 1.56(c) most knowledgeable about the content of the information, of each patent listed that is not in the English language, i.e., JP 9-208584. As such, the information disclosure statement has only been considered to the extent of the references that were provided. A signed copy of the IDS is attached hereto.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Claims 1-16 are rejected under 35 U.S.C. 102(a) as being anticipated by Shumach et al. (Arch. Dermatol. 38: 1165-1171, IDS).

Marks et al teach that imiquimod is an immune response modifier that is used for treating nasal basal cell carcinoma comprising administering an effective amount of imiquimod 5% cream (Title and page 1165, 1st column, 1st paragraph). With regards to the administration cycle, the reference teaches that in the 6 week study, imiquimod was applied once daily for 3 or 7 days per

week or twice daily for 3 or 7 days per week, and in the 12 week study, imiquimod was appled once daily for 3, 5 or 7 day per week, or twice daily for 7 days per week (page 1165, Interventions). With regards to the 12 week once daily 5 days per week, the reference teaches (page 1166, 2nd column, 2nd full paragraph) that imiquimod was applied on the same 5 consecutive says each week followed by 2 days without dosing. Moreover, the reference teaches (page 1166, 2nd column, 2nd full paragraph) that the cream was rubbed into and around (approximately up to 1cm) tumor and allowed to remain for at least 8 hours without occlusion.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* v. *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-12 and 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Marks et al. (J. Am. Acad. Dermatol. 2001; 44: 807-813, IDS) or Beutner et al. (J. Am. Acad. Dermatol. 1999; 41: 1002-1007, IDS) or Kagy et al. (Dermatol. Surg. 2000; 26: 577-579) or Geisse et al. (J. Am. Acad. Dermatol 2002; 47: 390-398, IDS).

Marks et al teach a method of treating superficial basal cell carcinoma comprising administering an effective amount of imiquimod 5% cream. With regards to the administration cycle, the reference teaches that nine patients were randomized to 6 weeks' application of iminquimod in 1 of the 4 treatment cycles: twice every day, once every day, twice daily 3 times/week, once daily 3 times/week (page 807, *Methods*). Moreover, Marks et al. teach that 100% of the twice daily treatment cycle had hisological clearance, 87.9 % clearance in the once every day

regimen, 73.3% clearance in the twice daily 3 times/week regiment, and 69.7% clearance in the once-daily 3 times/week treatment cycle.

Beutner et al. teach a method of treating basal cell carcinoma comprising administering an effective amount of imiquimod 5% cream. With regards to the administration, the reference teaches that 24 patients were treated for at least 6 weeks following 1 of the 5 treatment cycles: twice daily, once per day, three times weekly, twice weekly and once weekly (page 1003, 2nd column, *Study Results*). Moreover, Beutner et al. teach that 100% of the twice daily treatment cycle had complete clearance, 100% of the once daily, 100% of the three times weekly, 60% of the twice weekly and 50% of the once weekly (page 1004, 1st column, Table II).

Kagy et al. teach a method of treating superfacial basal cell carcinomas comprising administering an effective amount of imiquimod 5% cream. With regards to the administration, the reference teaches that one patient was treated for 18 weeks with a once daily application of 5% imiquimod cream, wherein after the 18th week the superfacial truncal BCC appeared to be eradicated (page 577, Top section, *METHODS* and page 578, 1st column, 1st full paragraph). In a commentary by John Geisse, the reference teaches that what remains to be defined for imiquimod treatment is the optimal dosing in which there can be three variables: concentration, which at the present time is fixed at 5% by available formulation, the frequency of application, and the duration of course of the therapy (page 578, 1st column, 4th paragraph of *Commentary*). With regards to the duration of therapy, the reference teaches that the optimal duration would be five out of seven days per week with duration of therapy of about 12 weeks (page 579, 1st column, last paragraph). Lastly, the reference teaches that further clinical trials are needed to determine the optimal dosing to minimize cutaneous side-effects and maximize efficacy (page 579, 2nd column, paragraph bridging 1st column).

Giesse et al. teach a method of treating superficial basal cell carcinoma comprising administering an effective amount of imiquimod 5% cream. With regards to the administration cycle, the reference teaches that patients were dosed twice daily, once daily, 5 times a week, or 3 times a week for 12 weeks (page 390, *Methods*). Moreover, Giesse et al. teach complete response rates in 100%, 87.1%, 80.8% and 51.7% for patients in the twice daily, once daily, 5 timers a week, and 3 times a week imiquimod groups, respectively, wherein the 5 times a week dosing for 12 weeks demonstrated high efficacy results with acceptable safety profiles (page 390, *Results* and *Conclusion*).

Marks et al., Beutner et al., Kagy et al. and Geisse et al. do not explicitly teach a treatment cycle that comprises at least two consecutive days or at least five consecutive days in which imiquimod is administered and at least one day or 2 days in which imiquimod is not administered. Nor do Marks et al., Beutner et al., Kagy et al. and Geisse et al. explicitly teach that the treatment area further comprises skin at least 0.5 cm beyond the margin of the lesion.

It would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to optimize the treatment cycle and treatment area for the administration of imiquimod as taught by Marks et al, Beutner et al., Kagy et al., and Geisse et al.. One would have been motivated to do so because while each of the references teach successful treatments of basal cell carcinoma, Geisse et al. (Commentary in Kagy et al.) teaches that further clinical trials are needed to determine the optimal dosing to minimize cutaneous side-effects and maximize efficacy. Furthermore, the Courts have found that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller*, 220 F2d 454,456,105 USPQ 233; 235 (CCPA 1955). see MPEP § 2144.05 part II A. As such, one would have a reasonable expectation of success that by optimizing the treatment cycle or treatment area of imiquimod to at least 2 or 5 days administration of imiquimod and at least one or two days of "rest" and at least 0.5 cm beyond the margin of the lesion, one would achieve an optimal method of treating basal cell carcinoma which minimizes the cutaneous side-effects.

Claims 13-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Marks et al. (J. Am. Acad. Dermatol. 2001; 44: 807-813) or Beutner et al. (J. Am. Acad. Dermatol. 1999; 41: 1002-1007) or Kagy et al. (Dermatol. Surg. 2000; 26: 577-579) or Geisse et al. (J. Am. Acad. Dermatol 2002; 47: 390-398, IDS) in view of Aldara™ (FDA, Labeling Revision 2001).

Marks et al., Beutner et al., Kagy et al. and Geisse et al. teach, as applied to claims 1-12 and 16 above, a method of treating basal cell carcinomas comprising administering an effective amount of imiquimod 5% cream.

Marks et al., Beutner et al., Kagy et al. and Geisse et al. do not explicitly teach that the imiquimod cream is applied to the treatment are for about eight hours.

Aldara™ teaches that Aldara™ is the brand name for imiquimod which is an immune response modifier used for the treatment of external genital and perianal warts/condyloma

acuminate in adults (page 3 and page 6, Indication and Usage). The labeling revision further teaches (page 12, Dosage and Administration) that Aldara cream should be applied to the target area prior to normal sleeping hours, and left on the skin for 6 to 10 hours.

It would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to apply the imiquimod cream to the treatment area as taught by Marks et al, Beutner et al., Kagy et al., and Geisse et al. for about 8 hours. optimize the treatment cycle and treatment area for the administration of imiquimod. One would have been motivated to do so because the Aldara labeling revision teaches (page 12, Dosage and Administration) that Aldara cream should be applied to the target area prior to normal sleeping hours, and left on the skin for 6 to 10 hours. As such, one would have a reasonable expectation of success that by applying the imiquimod cream to the treatment area as taught by Marks et al, Beutner et al., Kagy et al. and Geisse et al. for about 8 hours, one would achieve the optimal time for imiquimod treatment of basal cell carcinoma.

Claims 1-9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dogan et al. (Cancer Letters 1995; 91: 215-219).

Dogan et al. a method of treating basal cell carcinoma comprising administering intralesionally a therapeutically effective amount of alfa-2a interferon (abstract). With regards to the administration, the reference teaches that patients were treated for at least 4 weeks with alfa-2a interferon three times per week (page 217, Table 2). Moreover, Dogan et al teach that dispite the success rate of 84.6% in the present study, the success rate may be higher if the proper dose is applied in a proper duration with a longer post-treatment follow-up observation (page 218, 2nd column, last paragraph).

Dogan et al. does not explicitly teach a treatment cycle that comprises at least two consecutive days or at least five consecutive days in which interferon is administered and at least one day or 2 days in which interferon is not administered.

It would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to optimize the treatment cycle for the administration of interferon as taught by Dogan et al.. One would have been motivated to do so because Dogan et al. teach that dispite the success rate of 84.6%, the success rate may be higher if the proper dose is applied in a proper

duration. Furthermore, the Courts have found that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller*, 220 F2d 454,456,105 USPQ 233; 235 (CCPA 1955). see MPEP § 2144.05 part II A. As such, one would have a reasonable expectation of success that by optimizing the treatment cycle of interferon as taught by Dogan et al., one would achieve an optimal method of treating basal cell carcinoma with interferon.

Therefore, NO claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brandon J. Fetterolf, PhD whose telephone number is (571)-272-2919. The examiner can normally be reached on Monday through Friday from 7:30 to 4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeff Siew can be reached on 571-272-0787. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Brandon J Fetterolf, PhD
Examiner
Art Unit 1642

BF

JEFFREY SIEW
SUPERVISORY PATENT EXAMINER
3/29/06